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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/001,245 | 11/15/2001 | Jens Holm | 4305/1H942-US2 | 9286 |

7590

01/28/2005

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805 Third Avenue
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EXAMINER

NOLAN, PATRICK J

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/001,245 | Applicant(s) HOLM ET AL. | |
| | Examiner Patrick J. Nolan | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-85 is/are pending in the application.
- 4a) Of the above claim(s) 23,24,27,29-34,40-63 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,25,26,28,35,37-39,64 and 66-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3-7-02</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-35 and 37-85 are pending.
2. In applicant's listing of all pending claims as of November 26, 2002, there was no listing of claim 36. Clarification is required.
3. Applicant's election without traverse of Group I, claims 1-39, 64 and 66-85 in the reply filed on 7-3-04 is acknowledged.
4. Applicant's election of species SEQ ID NO. 219, without traverse, in the reply filed on 7-3-04 is acknowledged. As no prior art was found on SEQ ID NO. 219, the search was extended to an additional species and the art search was ended upon the finding of art on the additional species of a Bet v1 mutant.
5. Claims 23-24, 27, 29-34, 40-63 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7-3-04.
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.
7. Claims 1-22, 35, 64, 66-82 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/719,553 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if

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published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. The copending application discloses some of the same Bet v1 mutants, disclosed in the current application, for use in allergen therapy. See claim 26 in application 10/719,553 for example.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

8. Claims 1-22, 35, 64, 66-82 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Since the inventive entity in the current application is not the same as the inventive entity in 10/719,553 and the two applications are claiming the same subject matter, it is not known by the Examiner who the appropriate inventive entity is for the subject matter being claimed.

9. Claims 1-22, 35, 64-82 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/47680 (Reference 1 on the IDS submitted 3-7-02).

The '680 patent teaches making identical substitutions, 4 at least, to Bet v 1, to arrive at a mutant allergen (See page 16, lines 17-22 and claim 15, in particular). It appears to the Examiner the mutants are the same as what is currently being claimed. It is up to Applicant's to establish any patentable differences between the prior art mutants and the currently recited ones.

The prior art teachings anticipate the claimed invention.

10.. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-22, 35, 64, 66-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-27 of copending Application No. 10/719,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims arrive at similar allergenic variants, and by what appears to the Examiner by the same method of selection, or if not by an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 2, 4-14, 16, 18, 25, 26, 28, 35, 37-39, 64, 68-80, 83-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has elected SEQ ID NO. 19, as the elected allergen for prosecution. However upon a review of Applicant's specification and the amendment filed 6-30-04 for insertion of the objected to subject matter, there appears to be no written support for the sequence. In the specification Applicant states the six amino acid residues that can be mutated in the Der p 2, protein, and explicitly discloses the specific mutants made from said possible six amino acid residues, both in nucleic acid sequence and in the resulting amino acid sequence resulting therefrom. However, in none of those mutants was the six mutant protein made or contemplated. At no point in the specification or claims as originally filed, did applicant specifically disclose making a mutant with all 6 amino acid substitutions and as such they have no written support for the claims which SEQ ID NO. 219 reads upon.

14. The amendment filed 6-30-04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO. 218 and 219.

Applicant is required to cancel the new matter in the reply to this Office Action.

15. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

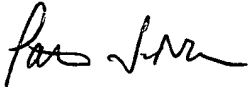
16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

A handwritten signature in black ink, appearing to read 'Patrick J. Nolan'.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

January 10, 2005